K081091

GE Healthcare

JUN 11 2008

510(k) Summary

The following 510(k) Summary was prepared in accordance with the requirements of 21 CFR §807.87(h) and §807.92.

(1) Identification of Submitter:

Submitter:	GE Healthcare
Address:	3000 N. Grandview Blvd W-709
Contact Person:	Michael Petrowski
Telephone #:	(262)-548-2673
Summary Prepared:	02-01-2008

Alternate Contact:

John L. Schmidt
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Safety & Regulatory Engineer
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3000 N. Grandview Blvd. W709
Waukesha, WI, 53188-1678, USA

(2) Device Information:

GE Model Name:	Precision 500D R&F X-ray System
Classification Name:	Image-intensified fluoroscopic x-ray system
Class:	Class II
Product Code:	JAA

(3) Predicate Device:

510(k) Number:	K011624
GE Model Name:	Precision 500D R&F X-ray System (Previous Name: Expedio 500D R&F X-ray System)
Classification Name:	Image-intensified fluoroscopic x-ray system
Class:	Class II
Product Code:	JAA

(4) Device Description:

The Precision 500D R&F X-ray System consists of an X-ray generator, angulating table with x-ray tube, collimator and image intensifier, wall stand, overhead tube suspension operator console and digital archive system

(5) Statement of Intended Use:

The Precision 500D R&F X-ray System is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic examinations, including general R&F and pediatric examinations.

The Precision 500D R&F X-ray Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic and fluoroscopic exposures of the whole body, skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position

(6) Technological Characteristic Comparison:

Design:

Precision 500D R&F X-ray System is identical in design and technology to the previously cleared Precision 500D R&F X-ray System K011624. There are no changes to the design and/or technology.

Material:

Precision 500D R&F X-ray System uses the exact construction materials as used in the previously cleared Precision 500D R&F X-ray System K011624. There are no changes to the materials.

Chemical Composition:

Chemical composition of materials is not critical for this type of device, because no material is implanted or inserted into the patient body or orifice to contact body tissues or fluids. Patient contact is not required for proper functioning of the device. See Section 15 for a statement regarding patient support tabletop material.

Energy Source:

The Precision 500D R&F X-Ray System uses the same energy source as was used in the previously cleared Precision 500D R&F X-ray System K011624: High Voltage Generator 3 Phase 80kW, Model Jedi 80TF2T, 2290800

Non-clinical Testing:

Bench testing verification was performed and a complete testing summary can be found in Section 18. Verification supports a minimum of 35% less dose when measured with a 32cm Image Intensifier (II) or 40cm II system in Pediatric Grid-in mode at 7.5 frames per second (fps) as compared to Adult Grid-in Mode at 30fps while comparatively quantifying image quality with a maximum difference in Signal to Noise Ratio (SNR) of 15%. Additionally verification supports a minimum of 35% less dose when measured with a

32cm II or 40cm II system in Pediatric Grid-in mode at 30fps as compared to Adult Grid-in Mode at 30fps while comparatively quantifying image quality with a maximum difference in SNR of 15%. Dose savings represent a minimum specification, averaged over all magnification modes, and SNR calculations are performed with "Iodine" selected as contrast agent.

Conclusion:

GE Healthcare considers the Precision 500D R&F X-ray System to be substantially equivalent to the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2008

Mr. Michael Petrowski
Safety & Regulatory Engineer
GE Medical Systems
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K081091
Trade/Device Name: Precision 500D R&F X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: February 1, 2008
Received: April 16, 2008

Dear Mr. Petrowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

GE Healthcare

Indication for Use

510(k) Number (if known): K081091

Device Name: Precision 500D R&F X-ray System

Indication For Use:
The Precision 500D R&F X-ray System is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic examinations, including general R&F and pediatric examinations.

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Prescription Use _____ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

_____
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

_____
(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number _____